UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

JAMES LE CARRE, individually and as Administrator and Administrator ad Prosequendum of the ESTATE OF ALEXANDER OLIN Plaintiffs.

v.

ALLIANCE HC II LLC d/b/a ANDOVER SUBACUTE AND REHABILITATION II; ALLIANCE HC 11 LLC d/b/a WOODLAND BEHAVIORAL AND NURSING CENTER; CHAIM SCHEINBAUM; LOUIS SCHWARTZ; SUBACUTE ANDOVER REHABILITATION II: WOODLAND BEHAVIORAL AND NURSING CENTER: JANE DOE NURSES 1-50; JANE ROE NURSES, TECHNICIANS, CNA'S AND PARAMEDICAL EMPLOYEES 1-50; JOHN DOE PHYSICIANS 1-50; RICHARD ROES 1-10; JANE DOE DIETICIANS 1-50; ABC CORPORATION AND ABC PARTNERSHIP (the aforesaid names being fictitious and their true names being unknown),

Defendants.

Civil Action No.: 3:21-cv-20226-MAS-DEA

Hon. Michael A. Shipp, U.S.D.J.

Oral Argument Requested

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF'S MOTION TO REMAND

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PRELIMINARY STATEMENT

The Public Readiness and Emergency Preparedness Act (PREP Act) provides broad immunity from suit and liability to private entities that have been enlisted by the federal government in the battle against COVID-19. Congress anticipated litigation that might arise from pandemics and other public disasters, and by way of the PREP Act, Congress afforded immunity to frontline licensed health care workers – including Defendants in this case – who are charged by the government with making decisions regarding the appropriate administration and use of covered countermeasures -- especially in the midst of a nationwide scarcity of such countermeasures -- to prevent the unprecedented transmission and spread of COVID-19. Moreover, as evidenced by the terms of the statute itself, Congress did not intend for any claims arising under the PREP Act to be litigated in state court; rather the Act was designed by Congress as a complete preemption statute, conferring exclusive federal jurisdiction over *all* claims of loss relating to COVID-19 countermeasures and any decisions as to their administration and use by those entities covered under the Act.

Here, regardless of how Plaintiff now attempts to recharacterize his claims in an apparent effort to achieve remand, Plaintiff's Complaint alleges unique facts and allegations that trigger complete preemption under the PREP Act. Plaintiff readily concedes that his claims arise from Defendants' use of covered countermeasures in responding to the COVID-19 pandemic, and importantly, Plaintiff clearly sets forth allegations of willful and intentional misconduct. This is significant because courts, including the Third Circuit in Maglioli v. Alliance Holdings LLC d/b/a Andover Subacute & Rehabilitation I, et al., (Nos. 20-2833 & 20-2834) (3rd Cir., October 20, 2021), agree that the PREP Act is a complete preemption statute with respect to claims of willful misconduct. These claims in this case are distinct from those made in Maglioli and in other cases on which Plaintiff relies. Thus, federal jurisdiction exists with respect to Plaintiff's claims, and this Court should, respectfully, exercise supplemental jurisdiction over any other remaining claims.

Also, notwithstanding Plaintiff's argument, this Court should not simply "rubberstamp" other distinguishable and erroneous remand decisions that are not final or under appeal. Rather, it is incumbent on

this Court to undertake its own independent analysis as to whether Plaintiff's claims fall within the purview of the PREP Act thereby invoking federal jurisdiction. Indeed, these issues are currently being considered by eight different Circuit Courts of Appeals across the country. Furthermore, Maglioli is not a binding authority as a petition for rehearing and rehearing en banc is pending before the Third Circuit given that the holding there contravenes Congressional intent underlying the PREP Act and binding Supreme Court precedent as to complete preemption. Equally important, however, is the fact that the claims as pled before this Court are wholly distinct and unique from those made by the plaintiffs in other cases including Maglioli. Therefore, Plaintiff's argument that this Court should blindly adopt any other holdings including the not-yet-final one in Maglioli—or that Defendants are somehow estopped from removing this case or are seeking a second bite of the apple—should be rejected outright.

Federal jurisdiction also exists here insofar as Defendants were acting at the direction of federal and state governments with regard to the conduct underlying Plaintiff's claims thereby affording them federal officer status and permitting the Court to exercise federal jurisdiction under 28 U.S.C. 1442(a)(1). Finally, this action, as with other COVID-19 actions alleging loss relating to the use and administration of covered countermeasures during the pandemic, presents a substantial federal question thereby creating federal jurisdiction under Grable & Sons Metal Products, Inc. v. Darue Engineering. & Manufacturing, 545 U.S. 308 (2005).

I. DEFENDANTS ARE NOT ESTOPPED FROM SEEKING REMOVAL HERE.

Plaintiff's Motion for Remand is based almost exclusively on the supposition that the Third Circuit decision in Maglioli v. Alliance Holdings LLC d/b/a Andover Subacute & Rehabilitation I, et al., (Nos. 20-2833 & 20-2834) (3rd Cir., October 20, 2021) binds this Court and estops Defendants from seeking removal in this case. Maglioli is not yet a final and binding decision by the Third Circuit, and that case is distinguishable from this one in any event.

A. Plaintiff Misstates the Standard for Collateral Estoppel.

Collateral estoppel prevents parties from re-litigating an issue if a court possessing personal and subject matter jurisdiction has already delivered a valid, final judgment on the merits. Witkowski v. Welch, 173 F.3d 192, 198-99 (3d. Cir. 1999). In the Third Circuit, the collateral estoppel doctrine applies only if: (1) the issue sought to be precluded is the same as that involved in the prior action; (2) that issue was actually litigated; (3) the issue was determined by a final and valid judgment; and (4) the determination was essential to the prior judgment. See In re Graham, 973 F.2d 1089, 1097 (3d Cir. 1992) (quoting In re Braen, 900 F.2d 621, 628-629 n.5 (3d Cir. 1979)). This test is consistent with that under New Jersey state law. See In re Estate of Dawson 136 N.J. 1, 20-21 (1994); Allen v. V & A Bros., 208 N.J. 114 (2011). Plaintiff's reliance on United Indus. Workers is entirely misplaced. United Indus. Workers involved an action in which a government employee filed a complaint for wrongful termination. After an arbitration board determined that his complaint was not covered by the applicable collective bargaining agreement, the plaintiff filed an action in the District Court seeking to vacate the dismissal of the complaint. When that petition was denied, Plaintiff appealed to the Third Circuit. The question before the Third Circuit was whether, "absent a collective bargaining agreement provision that requires arbitrators to be bound by earlier arbitration awards", the arbitrators can apply collateral estoppel to an earlier arbitration award. In that regard, the test applied by the Court (and which is not proposed by Plaintiff here) was specific to determinations made in the arbitration process. See United Indus. Workers v. Gov't of the V.I., 987 F.2d 162, 165 (3d Cir. 1993). Plaintiff attempts to employ this test from United Workers precisely because it omits the most critical aspect of the Third Circuit's well settled test for collateral estoppel – that is, the existence of a final determination on the relevant issue. Therefore, that case is inapposite.

B. Plaintiff Cannot Meet the Test for Collateral Estoppel.

There is no collateral estoppel here barring removal of this case to this Court based on Maglioli. By way of background, the Maglioli appeal is the first case in which a federal appellate court has considered jurisdictional arguments surrounding the complete preemptive effect of the PREP Act, the application of the federal officer removal statute to healthcare entities working at the direction of federal and state authorities during the COVID-19 pandemic, and whether the matters raised in these COVID-19 countermeasure cases

present a substantial federal question. The Third Circuit in <u>Maglioli</u> is only the one of multiple of Federal Circuit Courts presently considering these issues.

Notably, as of this date, <u>Maglioli</u> remains pending without a final mandate yet issued, as the defendants therein have moved for a rehearing by panel and a rehearing en banc pursuant to F.R.A.P. 35 & 30 on the basis that, *inter alia*, the holding therein contravenes Congressional intent underlying the PREP Act and binding Supreme Court precedent as to complete preemption. <u>See attached hereto as Exhibit A</u>, a true and accurate copy of the Petition for Rehearing in Maglioli v. Alliance Holdings LLC d/b/a Andover Subacute & Rehabilitation I, et al., (Nos. 20-2833 & 20-2834). Therefore, it remains to be seen whether the <u>Maglioli</u> decision – as it now stands — will become a final order. For that reason alone, Plaintiff's arguments fail as the decision in <u>Maglioli</u> has not been actually and fully litigated, and it is not binding on this Court despite Plaintiff's erroneous protestations otherwise.

Moreover, <u>Maglioli</u> is not even dispositive here as Plaintiffs' claims are unique and distinct from those asserted there; that is, the issue sought to be precluded is not the same as that involved and "actually litigated" in <u>Maglioli</u>. While the legal justification for removal may be similar as that raised in <u>Maglioli</u>, it is not identical because Plaintiff's Specific claims here are separate and distinguishable. Plaintiff's Complaint in this case alleges additional causes of action and theories of liability which were not present in <u>Maglioli</u>. As an initial matter, Plaintiff's Complaint very clearly includes multiple allegations of willful and intentional misconduct, which is the reason that the Court of Appeals in <u>Maglioli</u> ultimately found (albeit incorrectly) that there was not complete preemption under the PREP Act, as Court concluded that there was complete preemption "unambiguously" under the Act for willful claims. (Slip Opn at 25). Plaintiff's Complaint also alleges violations of various state and federal statutes including <u>N.J.S.A.</u> 30:13, <u>et seq.</u>, which criticizes Defendants' compliance with federal and state regulations and directives concerning the administration of covered countermeasures during the outbreak of COVID-19. **See attached hereto as Exhibit B, a true** and accurate copy of Plaintiff's Complaint, (ECF 1, Ex. A) at paras. 74-84. Finally, Plaintiff's allegations fall squarely within the purview of the PREP Act insofar as the Complaint is rife with additional

claims that Defendants mismanaged or otherwise acted improperly in the use or administration of multiple covered countermeasures including PPE and infection control instruments—such as, masks, gowns, facemask, and thermometers. <u>Id.</u> at Count IV, paras 15-25. Thus, while Plaintiff may attempt to color the basis for removal in this case as identical to <u>Maglioli</u>, by virtue of the unique allegations within Plaintiff's Complaint, the issues are decidedly dissimilar and <u>Maglioli</u> does not bind Defendants here, even if it was a final decision.

Accordingly, collateral estoppel is simply not applicable here, and it is incumbent upon this Court to undertake an independent analysis as to Defendants' basis for removal herein given the specific allegations raised in this Complaint by this specific Plaintiff.

II. THE PREP ACT COMPLETELY PREEMPTS PLAINTIFF'S CLAIMS

Pursuant to 28 U.S.C. § 1441(a), "[e]xcept as otherwise expressly provided by Act of Congress, any civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or the defendants, to the district in court of the United States for the district and division embracing the place where such an action is pending." Liberty Mut. Ins. Co. v. Ward Trucking Cor., 48 F.3d 142, 745 (3d Cir. 1995) (quoting 28 U.S.C. § 1441(a)). While a plaintiff is ordinarily entitled to choose a state or federal forum and may attempt to evade federal jurisdiction by pleading only state law claims, complete preemption is an exception to the well-pleaded complaint rule. See Metro-Life Ins. Co. v. <u>Taylor</u>, 481 U.S. 58, 64-64 (1987). Complete preemption occurs when the "pre-emptive force of a statute is so 'extraordinary' that it 'converts an ordinary state common-law Complaint into one stating a federal claim for purposes of the well-pleaded Complaint rule." Caterpillar Inc. v. Williams, 482 U.S. 386, 393 (1987) (quotation omitted); Metro-Life, 481 U.S. at 63-64 (complete preemption exists when the preemptive force of federal law is so powerful that it displaces any state law cause of action and leaves room only for a federal claim for purposes of the "well-pleaded complaint" rule). Complete preemption "confers exclusive federal jurisdiction in certain instances where Congress intended the scope of a federal law to be so broad as to entirely replace any state-law claim." Marin General Hosp. v. Modesto & Empire Traction Co., 581 F.3d 941, 945 (9th Cir. 2009) (quoting Franciscan Skemp Healthcare, Inc. v. Cent. States Joint Bd. Health & Welfare Trust Fund, 538 F.3d 594, 596 (7th Cir. 2008)) (internal quotations omitted).

According to the Third Circuit, complete preemption exists when: (1) a statute contains civil enforcement provisions within the scope of which a plaintiff's state law claims fall; and (2) there is a "clear indication of Congressional intention to permit removal despite the plaintiff's exclusive reliance on state law." Railway Labor Executives Ass 'n v. Pittsburgh & Lake Erie R.R. Co., 858 F.2d 936, 942 (3rd Cir. 1988) (citing Franchise Tax Bd. of State of Calif. v. Construction Laborers Vacation Trust for Southern Calif., 463 U.S. 1, 24 (1983)).

A. The PREP Act Provides an Exclusive Federal Cause of Action and Displaces State Law Claims, As Recognized by the Third Circuit and Other Courts.

The PREP Act is "unambiguously" a complete preemption statute, as confirmed by the Third Circuit in Maglioli: "the PREP Act's language easily satisfies the standard for complete preemption of particular causes of action." (Slip Opn. at 25). The U.S. Department of Health and Human Services ("HHS") in a January 2021 Advisory Opinion issued by its Office of General Counsel ("OGC") similarly has confirmed the PREP Act is a complete preemption statute that establishes an exclusive federal remedy for claims falling thereunder.

Congress enacted the PREP Act in December 2005 to encourage and coordinate a thorough, rapid, and comprehensive response to declared public health emergencies by granting broad immunity to covered persons (like Defendants) for claims of loss related to the administration or use of covered countermeasures, so that they may combat the emergency without fear of litigation or liability. See 42 U.S.C. § 247d-6d(a)(1). Specifically, the legislation empowers the Secretary of HHS to issue a written declaration and provide that a "covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure" during a health emergency. 42 U.S.C. § 247d-6d(a)(1). The HHS Secretary's declaration is controlling and cannot be reversed. Indeed, the PREP Act provides that "[n]o court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection." 42 U.S.C. § 247d-6d(b)(7).

Additionally, the PREP Act unambiguously creates an exclusive cause of action for, as is the case herein, allegations of death or serious physical injury proximately caused by willful misconduct. See 42 U.S.C. § 247d-6d(d)(l), as well as an exclusive federal remedy for claims that do no assert willful misconduct through the Covered Countermeasure Process Fund. It is thus clear that the PREP Act renders State causes of action for claims relating to covered countermeasures **impermissible**, as the PREP Act substitutes an exclusive federal cause of action and federal claims process in place of all state claims relating to the use and administration of covered countermeasures.

Moreover, in a subsection of the PREP Act conspicuously titled, "PREEMPTION OF STATE LAW," Congress provides, in relevant part, that "no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that is different from, or in in conflict with, any requirement applicable under this section" and relates to, among other things, use or administration of a covered countermeasure." 28 U.S.C. § 247d-6d(b)(8). Thus, any litigation arising from allegations under the PREP Act must be heard in federal court.

Accordingly, by these provisions in the PREP Act, Congress expressly directs that Plaintiff's claims here "shall be filed" in an exclusive specially appointed federal trial court, and nowhere else. See Claflin v. Houseman, 93 U.S. 130, 137 (1876). There is no test, no weighing of considerations, and, respectfully, no judicial discretion to be exercised: "the court conceded that Congress had the power to make the jurisdiction of its own courts exclusive." Id. at 42.

Indeed, multiple federal courts, including <u>Maglioli</u>, have found that the PREP Act easily satisfies the standard for complete preemption. In <u>Maglioli</u>, the Court noted:

The PREP Act's language easily satisfies the standard for complete preemption of particular causes of action. It provides an "exclusive cause of action ... and also set[s] forth procedures and remedies governing that cause of action." <u>Beneficial Nat'l Bank</u>, 539 U.S. at 8, 123 S.Ct. 2058.

(Slip Opn. at 26).

And the Third Circuit further pointed out:

The Supreme Court has relied on the complete preemptive force of a statute to infer congressional intent to create an exclusive federal cause of action.

Here, we have a better source of congressional intent: the words of Congress. Again, our analysis is straightforward. Congress said the cause of action for willful misconduct is exclusive, so it is.

Id.1

Other Courts have likewise addressed these issues and reached the same conclusion that "the PREP Act provides for complete preemption." In Garcia v. Welltower OpCo Grp. LLC, 522 F. Supp. 3d 734, 743 (C.D. Cal. 2021), the federal court declared: "[T]he PREP Act is a complete preemption statute." In Rachal v. Natchitoches Nursing & Rehabilitation Ctr. LLC, Case 1:21-cv-334, n.3 (W.D. La. April 30, 2021), another federal court stated unequivocally after sue analysis: "[T]he PREP Act is a complete preemption statute, thus creating a federal cause of action as specified therein." The District Court in the Western District of Louisiana further articulated that the PREP Act confers federal jurisdiction and completely preempts claims falling within its scope because it includes: 1) a civil enforcement provision that creates a cause of action that both replaces and protects the analogous area of state law; 2) a specific jurisdictional grant to the federal courts for enforcement of the right; and 3) a clear Congressional intent that claims brought under the federal law be exclusive. See id., supra, at fn.3.

B. HHS Under the Current and Prior Administration Agrees that the PREP Act is a Complete Preemption Statute.

For the COVID-19 pandemic, the PREP Act was invoked on March 10, 2020, when the HHS Secretary issued a Declaration under the PREP Act. The Declaration was effective as of February 4, 2020. In the Declaration, Secretary Azar declared that "Administration of Covered Countermeasures means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures." 85 Fed. Reg. 15198 (Mar. 17, 2020),

¹ Other Courts have come to the same conclusion. A very recent opinion from the District Court of South Carolina similarly recognized that the PREP Act is a complete preemption statute for certain claims. <u>Dozier v. Carlyle Senior Care of Kingstree, LLC</u>, No. 4:21-cv-01303-SAL (D.S.C. November 30, 2021); <u>Singer v. Montefiore</u>, No. 1:21-cv-02102, 2021 U.S. Dist. LEXIS 245930 (N.D. Ohio Dec. 27, 2021) (PREP Act is indeed a complete preemption statute for willful misconduct claims relating to the use or administration of covered countermeasures).

amended by 85 Fed. Reg. 21012 (Apr. 15, 2020), 85 Fed. Reg. 35100 (June 8, 2020), 85 Fed. Reg. 52136 (Aug. 24, 2020), 85 Fed. Reg. 79190 (Dec. 9, 2020), 85 Fed. Reg. 7872 (February 2, 2021), 86 Fed. Reg. 9516 (February 16, 2021), 86 Fed. Reg. 14462 (Mar.16, 2021), 86 Fed. Reg. 41977 (Aug. 4, 2021), and 86 Fed. Reg. 51160 (Sept. 14, 2021) (as corrected by 86 Fed. Reg. 54696 (Oct. 4, 2021)) (herein, "the Declaration").²

The Secretary, pursuant to the authority delegated to it by the PREP Act, has consistently updated the Declaration and relevant guidance in administering the PREP Act throughout the COVID-19 pandemic, using HHS's expertise to provide relevant and prudent guidance considering the evolving scientific understanding of the pandemic. Indeed, after careful analysis, the Secretary, and his Office has confirmed that these cases should be heard in federal court because, as designed by Congress, the PREP Act is a complete preemption statute, triggering exclusive federal jurisdiction. In response to litigation regarding these very issues, HHS issued a Fourth Amendment to the Declaration under the PREP Act on December 3, 2020. Therein, the Secretary confirmed that in order to effectuate the purpose underlying the PREP Act, Congress intended that COVID cases involving interpretation of the Act and covered countermeasures must be heard in the federal court system, as they raise substantial federal issues within the ambit of the Supreme Court's holding in Grable & Sons Metal Products, Inc. v. Darue Engineering. & Manufacturing, 545 U.S. 308 (2005).

On January 8, 2021, the OGC for HHS also issued AO 21-01, which is incorporated into the Secretary's Declaration and further confirms this reading of the Fourth Amendment. Evaluating conflicting policies based upon the state of the legal proceedings developing across the country, HHS confirmed that

² Secretary Azar subsequently issued an Amended Declaration under the PREP Act, which was effective as of March 27, 2020. The Amendment added respiratory protective devices approved by NIOSH (National Institute for Occupational Safety and Health) as a covered countermeasure under the PREP Act. On June 4, 2020, the Secretary further amended the March 10, 2020 Declaration to clarify that covered countermeasures under the Declaration include qualified products that limit the harm COVID-19 might otherwise cause. This Amendment was effective as of February 4, 2020. 85 FR 21012. Throughout the pandemic, HHS has reinforced the complete preemptive effect and the broad scope of the PREP Act in its Advisory Opinions and Amendments to the Declaration. To date, the Declaration has been amended ten (10) times, six (6) of which have been under the Biden Administration, further confirming the expansive breadth of the Act and its preemptive effect.

complete preemption is the logical and proper resolution based on the purpose of the Act as expressed in the statute, the scope of the Declaration, as well as relevant case law.

Moreover, the Biden Administration reaffirmed the breadth and complete preemptive effect of the PREP Act. On January 28, 2021, the HHS Secretary under the Biden Administration issued the Fifth Amendment to the Declaration explicitly confirming the Declaration, its Amendments and the AOs issued during the Trump Administration and reiterating that "[t]he plain language of the PREP Act makes clear that there is complete preemption of state law" and "preemption of State law is justified to respond to the nation-wide public health emergency caused by COVID-19..." The Secretary has since issued five additional amendments, continuing to expand the scope of the PREP Act, and confirming the prior Amendments and AOs. And the United States concurs with this position as set forth in its Statement of Interest filed in the Bolton v. Gallatin Center for Rehabilitation & Healing, LLC, wherein the United States likewise asserts the PREP Act is a complete preemption statute with respect to the administration or use of covered countermeasures. "Two key provisions of the PREP Act operate together to demonstrate its completely preemptive nature: the immunity provision and the exclusive alternative remedy provision." Thus, both the Trump and Biden Administrations agree – as does the Third Circuit and several other courts — that the PREP Act is a complete preemption statute as to certain claims.

Moreover, a number of other statutes that are similar to the PREP Act also have been held to establish complete preemption and original federal jurisdiction, such as the Labor Management Relations Act ("LMRA"),³ the Employee Retirement Income Security Act ("ERISA),⁴ the Federal Tort Claims Act

Any state law claims that are substantially dependent on analysis of a collective-bargaining agreement are completely preempted by section 301 of the LMRA and must be brought in federal court. <u>Caterpillar Inc. v. Williams</u>, 482 U.S. 386, 393 (1987). However, before an employee may bring a Section 301 claim in court, the employee must "at least *attempt to exhaust exclusive grievance and arbitration procedures* established by the [collective] bargaining agreement." <u>Campbell v. Kane, Kessler, P.C.</u>, 144 F. App'x 127, 130 (2d Cir. 2005) (quotation omitted) (Emphasis added.)

⁴ ERISA is another complete preemption statute that has a "firmly established federal policy favoring exhaustion of administrative remedies" for purposes of, *inter alia*, reducing the number of frivolous lawsuits, providing a non-adversarial method of claims settlement and minimizing the costs of claims settlement for all. <u>Kennedy v. Empire Blue Cross & Blue Shield</u>, 989 F.2d 588, 594 (2d Cir. 1993); <u>Paese v. Hartford Life & Acc. Ins. Co.</u>, 449 F.3d 435,445 (2d Cir. 2006).

("FTCA"),⁵ and the Air Transportation Safety and System Stability Act ("ATSSSA").⁶ The PREP Act is a similar statute and should be held to be a complete preemption statute by this Court as well.

C. Plaintiff's Claims are Completely Preempted by the PREP Act.

i. Plaintiff Alleges Willful and Intentional Misconduct.

In an apparent effort to circumvent the unequivocal complete preemptive effect of the PREP Act, Plaintiff now attempts to recast the allegations in his Complaint, arguing that they are identical to those asserted in Maglioli. However, nothing could be farther from reality. A plain reading of Plaintiff's actual Complaint reveals that Plaintiff makes multiple claims of willful and intentional misconduct regarding countermeasures that far exceed the alleged "boiler plate" punitive damage claims (as they have been characterized) which were analyzed in Maglioli. For example, in Count IV of the Complaint, Plaintiff specifically pleads causes of action for willful misconduct, alleging Defendants' conscious disregard for the health and safety of others by increasing the risk of contraction and transmission of COVID-19 to residents given, *inter alia*, their "conscious" decisions and choices as to purchasing, providing, maintaining and/or monitoring the numbers of PPE available to its employees and staff. Exhibit B at Count IV, paras. 14, 15; Count IV, par. 17.

Plaintiff further alleges specific willful misconduct by Defendants particularly with regard to covered countermeasure, such as PPE, stating, *inter alia*:

- how they implemented their COVID-19 infection control and prevention procedures;
- how they monitored the level and amount of PPE available for staff and employees;
- how they enforced PPE utilization and hand washing procedures;

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⁵ The FTCA, which is strikingly similar to the PREP Act, immunizes certain persons from liability and also provides an administrative/judicial remedial scheme for claims falling thereunder. The FTCA affords liability protection to federal employees for any negligent or wrongful acts committed while acting within the scope of their employment, and provides an exclusive federal cause of action in the federal district courts against the United States under specified circumstances. Like the PREP Act, before a judicial action may be instituted, the claimant must first present the claim before the appropriate federal agency for adjudication. 28 U.S.C. § 2675. This jurisdictional requirement cannot be waived, Celestine v. Mount Vernon Neighborhood Health Ctr., 403 F.3d 76, 82 (2d Cir. 2005), resulting in the dismissal of claims where a claimant fails to exhaust the administrative remedies.

⁶ Congress passed the ATSSSA after the September 11th terrorist attacks to create an exclusive federal cause of action for damages "arising out of the hijacking and subsequent crashes" of the aircraft used in the attacks. ATSSSA § 408(b)(l), 49 U.S.C. § 40101. Like the PREP Act, the ATSSSA also includes a victim's compensation fund. Similar to the PREP Act, Congress' principal goals in enacting the ATSSSA "were to provide relief *without litigation* to individuals harmed as a result of the crashes and to *limit the liability of entities* that were likely to be sued for injuries suffered in connection with the crashes." In re WTC Disaster Site, 414 F.3d 352, 377 (2d Cir. 2005) (Emphasis added).

- how they purchased and provided PPE for all residents. (Count IV, par. 21 (a-p));
- how they measured and conserved PPE for professional healthcare workers and other staff;
- how often they disinfected frequently touched areas; and
- how they allocated PPE to positive/symptomatic residents. (Count IV, par. 22 (a-cc).

Additionally, Plaintiff alleges that Defendants violated the Nursing Home Cares Act by: intentionally failing to develop proper COVID-19 isolation control and prevention – countermeasure --policies and procedures; intentionally failing to screen residents which also implicates countermeasures; intentionally failing to maintain, monitor and/or employ standard contact and droplet precaution and PPE; intentionally failing to purchase, provide, maintain, monitor and/or employ adequate PPE; and intentionally failing to provide alcohol-based hand disinfectant/hygiene products. Id. at Count IV, par. 24 (a-bb)).

In Maglioli, the Court did not find that the plaintiffs' had asserted any claims for intentional or willful misconduct because the operative Complaint in that action asserted a cause of action for punitive damages which — according to the Court — did not, without more, specifically include allegations of willful or intentional wrongs. (Slip Opn. at 30). While Defendants herein contend the Third Circuit's finding in that regard was in error, it is does not affect this Court's analysis here. Plaintiff in this case has made clear and specific allegations of intentional and willful misconduct despite what Plaintiff may now claim in his remand motion. Moreover, Plaintiff cannot hide behind the title of his Fourth Count as Plaintiff cannot "have his cake and eat it too" in deliberately seeking to circumvent the statute while still explicitly and substantively pleading claims for willful misconduct against Defendants. Indeed, the Fourth Count of the Complaint is rife with allegations against Defendants that they acted with wrongful purpose and/or intentionally acted in ways that would cause harm to Plaintiff. This is precisely the type of willful misconduct that triggers the PREP Act. And as the Third Circuit stated, the question is "whether the estates could have brought their claims under the PREP Act's cause of action for willful misconduct." (Slip Opn. at 27); see also Prince v. Sears Holdings Corp., 848 F.3d 173 (4th Cir. 2017) ("Defendants may remove preempted state law claims to federal court, regardless of the 'label' that the plaintiff has used.").

Although Defendants contend that the Third Circuit in Maglioli wrongfully found that plaintiffs there did not plead willful misconduct, what is not disputed is that Maglioli confirms unequivocally that allegations of willful misconduct are completely preempted under the statute. Thus, this Court has jurisdiction over Plaintiff's expressly pled willful misconduct allegations and should thereafter exercise supplemental jurisdiction over any other remaining claims pursuant to 28 U.S.C. § 1367. Moreover, so long as one claim triggers complete preemption, there is federal jurisdiction over the entire suit. Smallwood v. Allied Van Lines, Inc., 550 F.3d 1115, 1120 (9th Cir. 2011); see also Goles v. NYL Care Health Plans, Inc., 172 F. 3d. 332, 337 (5th Cir. 1999).

D. Plaintiff's Other Claims are Also Completely Preempted under the PREP Act.

The complete preemptive force of the PREP Act, however, is not limited to only allegations of willful misconduct. Such a narrow reading would be contrary to and inconsistent with the broad purposes of the PREP Act to provide a unified, rapid federal response to a national public health threat and to prevent critical partners from being distracted by the cost and conflicting standards of litigation in multiple forums. Declaration, 85 Fed. Reg. 15, 195. Defendants maintain that the PREP Act is a complete preemption statute as to all claims regardless of whether the standard of liability is one of willfulness or one of negligence. The Court in Maglioli erred in this regard and thus a rehearing petition is pending before the Third Circuit.

In <u>Maglioli</u> the Court concluded the PREP Act creates and completely preempts a "willful misconduct" cause of action but erred in finding the Act did not completely preempt all of plaintiffs' claims there so as to create subject-matter jurisdiction because, according to the Court, those plaintiffs did not allege willful misconduct, which "is a separate cause of action from negligence." (Slip Opn. at 28). When determining whether complete preemption applied to plaintiffs' claim, the Court recited the test set forth in <u>Davila</u>, 542 U.S 200, but then misapplied it and consequently rendered a decision inconsistent with that precedent.

In <u>Davila</u>, the Court analyzed whether the plaintiffs' state-law causes of action against an HMO for refusal to cover services in violation of the Texas Health Care Liability Act were preempted by the civil enforcement mechanisms contained in section 502(a) of ERISA, 29 U.S.C. § 1132(a). 542 U.S. at 204. Noting

that the purpose of ERISA is to provide a "uniform regulatory regime over employee benefit plans" and that the statute represents "a careful balancing of the need for prompt and fair claims settlement procedures against the public interest in encouraging the formation of employee benefit plans," the Court concluded that Congress rejected any state-law remedies. <u>Id</u>. at 208. The Court reasoned that any such remedies would "completely undermine[]" Congress' policy choices reflected in the inclusion of certain remedies and exclusion of others. <u>Id</u>. at 208–09. Accordingly, the Court instructed that "any state-law cause of action that duplicates, supplements, or supplants the ERISA civil enforcement remedy conflicts with the clear congressional intent to make the ERISA remedy exclusive and is therefore pre-empted." <u>Id</u>. at 209.

As the Supreme Court instructed, the elements of a federal cause of action need not duplicate state causes of action in order to provide complete preemption:

Nor would it be consistent with our precedent to conclude that only strictly duplicative state causes of action are pre-empted. Frequently, in order to receive exemplary damages on a state claim, a plaintiff must prove facts beyond the bare minimum necessary to establish entitlement to an award....In order to recover for mental anguish, for instance, [a plaintiff]...would presumably have had to prove the existence of mental anguish; *there is no such element* in an ordinary suit brought under ERISA § 502(a)(1)(B)....*This did not save these state causes of action from pre-emption.* Congress' intent to make the ERISA civil enforcement mechanism exclusive would be undermined if state causes of action that supplement the ERISA § 502(a) remedies were permitted, even if the elements of the state cause of action did not precisely duplicate the elements of an ERISA claim.

Id. at 216 (citations omitted) (emphasis added).

The Maglioli holding is contrary to Davila in concluding only allegations that strictly track the definition of willful misconduct in the PREP Act are completely preempted. The PREP Act is completely preemptive, even if plaintiffs' state-law claims are not "strictly duplicative" of a cause of action under the PREP Act. A PREP Act cause of action sounds in tort. 42 U.S.C. § 247d-6d(d)(1)–(2) (creating cause of action for "wrongful death or serious physical injury"). The elements of a PREP Act cause of action are: duty (id. at § 247d-6d(b), (d)(1)); breach (id. at § 247d-6d(c), (e)(3)(A)); causation (id. at § 247d-6d(e)(3)(B)); and injury/loss (id. at § 247d-6d(a)(2)(A), (e)(3)(C)). The PREP Act sets a standard of liability (id. at § 247d-6d(c)(1)) and a burden of proof (id. at § 247d-6d(c)(3)). The ways in which the PREP Act duties can be breached are itemized in § 247d-6d(c)(1)(A).

Willful misconduct is not the cause of action; it is a standard of liability that is part of the PREP Act federal cause of action. 42 U.S.C. § 247d-6d(c), (c)(1)(B). The PREP Act provides an exclusive federal cause of action for a "person who suffers" an injury relating to a COVID-19 countermeasure, program, or facility, at the hands of a "covered person." Whether the claims asserted meet the standard of liability to state a claim upon which relief may be granted is within the exclusive province of the specially appointed federal court in Washington, D.C., not a state court. 42 U.S.C. § 247d-6d(d)(1)–(2), (e)(1), (e)(5).

Further, there is no such thing as partial complete preemption as the opinion suggests. Once an exclusive federal cause of action has been created, all actions within that category (e.g., tort claims arising from countermeasure use, programs or facilities) are completely preempted regardless of the standard of liability. Davila, 542 U.S. at 215–16; Beneficial, 539 U.S. at 8. Some of those claims may be brought in federal court if the standard of liability for willful misconduct can be shown. For any other claim for loss, Congress provides a no-fault, fully-funded federal administrative claims process that provides compensation.

The <u>Maglioli</u> Court recognized that removal is proper "if the federal statute 'wholly displaces the state-law cause of action through complete pre-emption." (Slip Opn. at 21, quoting <u>Beneficial</u>, 539 U.S. at 8). It affirmed that the proper inquiry is whether the federal remedy is *exclusive*. (<u>Id</u>. at 21–22, n.9.) That should resolve the issue because the PREP Act is precisely the type of statute described by the Supreme Court as completely preemptive. The Act further provides for immunity from suit or liability for all claims for loss (42 U.S.C. § 247d-6d(a)(1)) and an exclusive remedy of a no-fault compensation fund for injuries (§ 247d-6e), with only a narrow exception for claims that meet the standard of liability for willful misconduct claims, which is expressly designated as an "exclusive federal cause of action" (§ 247d-6d(d)(1)). In that way, the federal remedies under the PREP Act are wholly exclusive—evincing Congressional intent to completely displace state-law claims with the exclusive federal remedial scheme.

Allowing for state court causes of action for negligence that "supplement or supplant" the exclusive federal remedies provided for in the PREP Act is inconsistent with the Supreme Court's instruction in <u>Davila</u> that allowing state-law causes of action would conflict with the clear congressional intent to make the PREP Act remedy exclusive. <u>Davila</u>, 542 U.S. at 209. While a federal cause of action is sufficient to demonstrate

complete preemption, it is not the *only* way to demonstrate complete preemption. A statute providing only for an administrative fund has been found to effect a complete preemption of all state-law claims. A number of cases have found the Civil Service Reform Act of 1978 (CSRA), although providing only an administrative remedy and limited judicial review, provides the exclusive remedy for the conduct alleged. In <u>Karahalios v. National Federation of Federal Employees</u>, <u>Local 1263</u>, 489 U.S. 527, 536 (1989), the Supreme Court concluded the administrative remedy provided under the CSRA excluded other implied remedies. In <u>Bush v. Lucas</u>, 462 U.S. 367, 388 (1983), the Court considered the regulatory structure of the CSRA and recognized that Congress may construct a remedial system that may not provide complete relief for the plaintiff, but that does not negate the completely preemptive effect of the statute. <u>Bush</u> recognized that its holding might provide less than complete protection to federal employees, but the Court hesitated to upset the CSRA's "elaborate remedial system that has been constructed step by step, with careful attention to conflicting policy considerations[.]" Id.

Indeed, allowing state claims "would interfere with the congressional objective of making the CSRA an 'exclusive' forum for challenging federal personnel actions." Saul v. United States, 928 F.2d 829, 841 (9th Cir. 1991). Saul inferred that Congress did not mention any state tort law remedies "because it left no room for them." Id. at 842. In Schwartz v. International Federation of Professional & Technical Engineers, 306 F. App'x 168, 172 & n.5, 174 (5th Cir. 2009), the court concluded that although the CSRA offered only an administrative remedy, it was indeed a complete preemption statute supporting federal court jurisdiction, even though it left the plaintiff without a remedy for his state-law intentional infliction of emotional distress claim.

This is consistent with Third Circuit precedent. In <u>Sarullo v. United States Postal Service</u>, 352 F.3d 789, 795 (3d Cir. 2003), the Third Circuit found subject-matter jurisdiction lacking over the plaintiff federal employee's claims because the "case ar[ose] out of the employment context and...the CSRA therefore provides the full scheme of remedies available"); <u>see also Whiting v. United States Army</u>, No. 08-435 (JLL), 2008 U.S. Dist. LEXIS 71734, at *11–12 (D.N.J. Sept. 4, 2008) (gravamen of the complaint fits within the CSRA statutory scheme and is thus preempted).

Under these courts' reasoning, the PREP Act, too, is Congress' expression of a carefully structured balance of conflicting interests that may result in a recovery that is different than that allowed under state law. Like the CSRA, the PREP Act leaves "no room for [state tort remedies] to operate. Saul. 928 F.3d at 843. In the PREP Act, Congress has engaged in the same careful balancing of the need for prompt and fair claims settlement procedures (and limited litigation options) against the public and national interest in encouraging a unified, rapid federal response to a national public health threat and to prevent critical partners in that effort from being dissuaded or derailed by the cost and conflicting standards of litigation in multiple forums. Declaration, 85 Fed. Reg. 15198 (Mar. 17, 2020); Fourth Amended Declaration, 85 Fed. Reg. 79190–91 (Dec. 9, 2020); see also Davila, 542 U.S. at 208. Congress carefully constructed the PREP Act to provide exclusive remedies that completely displace state-law claims. Allowing state claims, as the panel does, interferes with the carefully constructed congressional scheme.

In sum, the PREP Act therefore completely preempts <u>all</u> Plaintiff's claims regardless of whether the Court chooses to follow the narrower approach in <u>Maglioli</u> or the approach of the Supreme Court in <u>Davila</u>.

E. Plaintiff Does Not Dispute That Defendants' Conduct Falls Squarely Within the Purview of the PREP Act.

In the face of a national public health threat like that posed by the COVID-19 pandemic, Congress delegated extraordinarily broad authority to the HHS Secretary. 42 U.S.C. § 247d-6d(b)(1). By Congress' explicit directives in the PREP Act, and particularly by making the actions of the Secretary non-reviewable, Congress intended the Secretary's declaration (including any amendments) interpreting the scope of the Act to have the force of law. As the Secretary states: "Through the PREP Act, Congress delegated to me the authority to strike the appropriate Federal-State balance with respect to particular Covered Countermeasures through PREP Act declarations." 85 Fed. Reg. 79198.

Significantly, in <u>Maglioli</u>, the Third Circuit confirmed the HHS Secretary's broad authority – which it explicitly recognized as controlling on the courts -- to define what constitutes the "use" or "administration" of covered countermeasures and what conduct -- including what "acts and omissions" -- fall within the scope of the PREP Act. (Slip Opn. at 8). Indeed, the Secretary has done so in the Declaration and the ten

amendments thereto as well as the six AOs issued by the Office of the Secretary regarding the expansive scope of the PREP Act.

Plaintiff, in his remand motion, does not dispute that the allegations contained in the Complaint involve the use and administration of a multitude of covered countermeasures which are protected under the PREP Act. Plaintiff only argues that this matter should not be heard in federal court.

i. Defendants are Covered Persons under the Act.

The PREP Act applies to "covered persons" who administer or use a "covered countermeasure" during a "recommended activity" in relation to COVID-19. 42 U.S.C. § 247d-6d. 46. Pursuant to the Act, a "covered person" includes (i) the United States; (ii) manufacturers and distributors of covered countermeasures; (iii) program planners; and (iv) qualified persons who prescribe, administer or dispense covered countermeasures. 42 U.S.C.§ 247d-6d(i)(2). 47. "Qualified persons" include licensed health professionals and other individuals authorized to prescribe, administer, or dispense covered countermeasures under state law, as well as other persons identified in a declaration by the Secretary. 42 U.S.C. § 247d-6d(i)(8). "Program planners" include state and local governments or other persons who supervise or administer programs that dispense, distribute, or administer covered countermeasures, *or* provide policy guidance, facilities, and scientific advice on the administration or use of such countermeasures. 42 U.S.C. § 247d-6d(i)(6). The meaning of "program planner" and "qualified person" has been clarified as follows:

...State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with [the Secretary's declaration].

42 U.S.C. § 247d-6d[i][6].

Under the Secretary's declaration, "[A] private sector employer or community group or other 'person' can be a program planner when it carries out the described activities." 85 Fed. Reg. at 15,202. Furthermore, on August 14, 2020, the HHS Office of General Counsel confirmed that senior living

communities are "covered persons" subject to immunity under the PREP Act as "program planners" and "qualified persons." [OGC Letter to Thomas Barker.] The Office of General Counsel also published a Guidance confirming that COVID testing in nursing homes is a covered countermeasure triggering the Act. ⁷ 52. On October 23, 2020, the HHS Office of the General Counsel's Advisory Opinion No. 20-04 ("AO 20-04") verified that the term "program planner" is broadly defined. The opinion also explained that PREP Act coverage will apply to a covered person using a covered countermeasure in accordance with any public health guidance from an "Authority Having Jurisdiction." The January 8, 2021 AO 21-01 more broadly outlined that a "program planner" under the Act is "someone who is involved in providing or allocating covered countermeasures," and that "program planning inherently involves the allocation of resources." The Advisory Opinion thereby concluded that "decision-making that leads to the non-use of covered countermeasures by certain individuals is the grist of program planning and is expressly covered by [the] PREP Act."

Thus, Defendants qualify as "covered persons" under the PREP Act. During the time set forth in the underlying Complaint, Defendants acted as both "qualified persons" and "program planners." Defendants operated as a skilled nursing facility licensed by the New Jersey Department of Health. As part of the operation of the facility defendants allocated gloves, gowns and masks to residents and staff to preserve scarce PPE and use it consistently with evolving guidance and directives from CMS and the NJ DOH. The claims regarding Defendants Chaim "Mutty" Scheinbaum and Louis Schwartz, whom are being sued in their respective capacities as owners, are derivative to those directed at the two nursing facility Defendants.

ii. Plaintiff's Claims Arise from Defendants' Use and Administration of "Covered Countermeasures."

The PREP Act is applicable with respect to a "covered countermeasure," which by definition includes: "(1) a qualified pandemic or epidemic product (as defined in § 247d-6d (i)(7))... or (4) a respiratory protective device that is approved by the National Institute for Occupational Safety and Health ("NIOSH") and that the Health and Human Service Secretary determines to be a priority for use during a public health

⁷ HHS, Office of the General Counsel, Letter to Thomas Barker, Foley Hoag LLP (Aug. 14, 2020) *available at* https://www.govinfo.gov/content/pkg/FR-2020-08-24/pdf/2020-18542.pdf [Aug. 31, 2020].

emergency declared under section 247d." 42 U.S.C. § 247d-6d(i)(1). A "qualified pandemic or epidemic product" is defined as: a drug, biologic product or device that is:

"(A)(i) a product manufactured, used, designed, developed, modified, licensed, or procured—

- (I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or
- (II) to limit the harm such pandemic or epidemic might otherwise cause;
- (ii) a product, manufacture, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious of life-threatening disease or condition caused by a product described in clause (i); or
 - (iii) a product or technology intended to enhance the use or effect of a drug, biologic product, or device described in clause (i) or (ii); and
- (B)(i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act or licensed under section 262 of this title;
- (ii) the object of research for possible use as described in subparagraph (A) and is the subject of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act; or
 - (iii) authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug and Cosmetic Act."

See 42 U.S.C. § 247d-6d(i)(7).

The March 17, 2020 Declaration expanded the categories of "covered countermeasures" eligible for immunity to include *any* device used to treat, diagnose, cure, prevent or mitigate COVID-19 or its spread. The Declaration was subsequently amended to add respiratory protective devices like N95 masks to the list of covered countermeasures. See 42 U.S.C. § 247d-6d(i)(1)(D); see also 85 Fed. Reg. at 21,014. Also, in response to the Coronavirus Aid, Relief, and Economic Security (CARES) Act § 3103, Pub. L. No. 116-136 (March 27, 2020), the PREP Act COVID-19 declaration was amended to add respiratory protective devices to the list of covered countermeasures so long as they are NIOSH approved and determined by the Secretary to be a priority for use during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act.5 See 42 U.S.C. § \$ 247d, 247d-6(i)(1)(D). On June 8, 2020, the Declaration was amended again to reflect the HHS's original intent to "identify the full range of qualified countermeasures" as permitted under the PREP Act. 85 Fed. Reg. 35100. Thus, a covered countermeasure includes a broad range of products and devices specified as: (i) a qualified pandemic or epidemic product; (ii) a security countermeasure; (iii) a drug, biological product, or device that the U.S. Food and Drug Administration (FDA) has authorized for emergency use; and, (iv)a NIOSH-approved respiratory protective device. Plaintiff's

claims related to such countermeasures including PPE such as facemasks, gloves, gowns, face shields, N95 masks, COVID testing materials, thermometers, and other items which qualify as pandemic or epidemic products under the PREP Act.

In the present matter, Plaintiff's Complaint on its face alleges claims arising from the manner in which the Andover facility administered and allocated PPE and other COVID-19 covered countermeasures to individuals within the facility, including staff and residents. Thus, the PREP Act is applicable to claims being made by Plaintiff. Moreover, Plaintiff's claim for damages derive almost exclusively from Defendants' alleged failure to manage, distribute, or otherwise utilize PPE and other countermeasures in treating Mr. Olin.

III. JURISDICTION EXISTS UNDER THE FEDERAL OFFICER REMOVAL ACT.

Removal is also proper under 28 U.S.C. § 1442(a)(1), which provides for removal when a defendant is sued for acts undertaken at the direction of a federal officer. Under the federal officer removal statute, a federal court has jurisdiction over a civil action that is directed at "[t]he United States or any agency thereof or any officer (or any person acting under that officer) of the United States or of any agency thereof, in an official or individual capacity, for or relating to any act under color of such office." 28 U.S.C. § 1442(a)(1). The statute is premised on the existence of a "federal interest in the matter," and the need to enforce "federal law through federal officials." Willingham v. Morgan, 395 U.S. 402, 406 (1969) ("right of removal under § 1442(a)(1) is made absolute whenever a suit in a state court is for any act 'under color' of federal office, regardless of whether the suit could originally have been brought in a federal court"). Unlike the general removal statute, the federal officer removal statute is to be "broadly construed" in favor of a federal forum. See Sun Buick, Inc. v. Saab Cars USA, Inc., 26 F.3d 1259, 1262 (3d Cir. 1994); In re Commonwealth's Motion to Appoint Counsel, 790 F.3d 457, 466-67 (3d Cir. 2015) ("Defender Ass'n"). Removal was proper here insofar as "(1) Defendants are 'persons' within the meaning of the statute; (2) Plaintiff's claims are based upon Defendants' conduct 'acting under' the United States, its agencies, or its officers; (3) Plaintiff's claims are 'for, or relating to' an act under color of federal office; and (4) Defendants raise a colorable federal defense to Plaintiff's claims." Papp v. Fore-Kast Sales Co., 842 F.3d 805, 811 (3d Cir. 2016). All requirements for removal under § 1442(a)(1) are thus satisfied here.

A. Defendants are "Persons" Within the Meaning of the Statute.

Defendants are all "persons" under the federal officer removal statute. Alliance HC 11 LLC is a corporate entity, and corporations are "person[s]" pursuant to Section 1442(a)(1). Papp, 842 F.3d at 812 (for purposes of Section 1442(a), "a corporation is in legal fact a person" (citing 1 U.S.C. § 1)). Remaining Defendants Chaim Scheinbaum and Louis Schwartz are individuals acting as owners/officers of the aforementioned entities.

B. Defendants Were "Acting Under a Federal Officer."

i. Plaintiff Mischaracterizes and Misapplies Defendants' Position Regarding the "Program Planner" Designation.

Plaintiff erroneously contends that Defendants have failed to argue that they were "program planners" administering programs that dispensed covered countermeasures as part of federal effort to combat COVID-19. This is simply false. Defendants have argued their status as "program planners" in other matters including before the Third Circuit in Maglioli. Moreover, to date, no Court has specifically determined that Defendants do not qualify as program planners with respect to the administration of covered counter measures. As previously set forth, under the PREP Act, a private sector employer or other person can be a "program planner" when it carries out prescribed activities during the COVID-19 pandemic. HHS issued a letter which provided that senior living communities such as Defendants meet the definition of "program planner" to the extent that it supervises or administers a program with respect to the administration, dispensing, distribution, provisions or use of a qualified pandemic or epidemic product.

ii. Defendants Satisfy the "Acting Under" Requirement of the Statute.

To satisfy the second requirement ("acting under" a federal officer) "a private person's actions 'must involve an effort to assist, or to help carry out, the duties or tasks of the federal superior." Watson, 551 U.S. at 152. Federal courts "have explicitly rejected the notion that a defendant could only be 'acting under' a federal officer if the complained-of conduct was done at the specific behest of the federal officer or agency." Papp, 842 F.3d at 813. A private party need not act as an agent of a federal agency. Rather, it is enough that the person is acting on behalf of the officer in a manner *akin* to an agency relationship. Doe v. UPMC, No.

2:20-cv-359, 2020 U.S. Dist. LEXIS 136077, at *9 (W.D. Pa. July 31, 2020); City of San Mateo v. Chevron Corp., 960 F.3d 586, 599 (9th Cir. 2020) (citing Watson, 551 U.S. at 151). In particular, the Supreme Court noted that federal officer jurisdiction can be found "[w]here a private person acts as an assistant to a federal official in helping that official to enforce federal law." Id. The Supreme Court stated:

[T]he removal statute applies to private persons "who lawfully assist" the federal officer "in the performance of his official duty" ... if they were "authorized to act with or for [federal officers or agents] in affirmatively executing duties under ... federal law."

<u>Watson</u>, 551 U.S. at 151 (quoting <u>Davis v. South Carolina</u>, 107 U.S. 597, 600 (1883) and <u>City of Greenwood v. Peacock</u>, 384 U.S. 808, 824 (1966)). <u>Watson</u> states: "A private firm's compliance (or noncompliance) with federal laws, rules, and regulations does not *by itself* fall within the scope of the statutory phrase 'acting under' a federal 'official' even if the regulation is highly detailed and even if the private firm's activities are highly supervised and monitored." <u>Id.</u> at 153 (emphasis added). <u>Watson</u> thus plainly recognizes that the words "acting under" mean "[s]ubject to the instruction, direction, or guidance of." The Supreme Court signaled by its use of the words "by itself" that it intended to leave open the prospect of affording federal removal jurisdiction to private persons in those circumstances where there is *something more*.

Here, Defendants were subject to "direct and detailed control," rather than "under the general auspices of a federal officer." Paldrmic v. Altria Corp. Servs., Inc., 327 F. Supp. 2d 959, 964 (E.D. Wis. 2004). "Critical under the statute is to what extent defendants acted under federal direction at the time they were engaged in the conduct now being sued upon." Ryan v. Chemical Co., 781 F. Supp. 934, 947 (E.D.N.Y. 1992) (private party can remove if it can show that conduct for which it is being sued is "closely linked to detailed and specific regulations"). This test has been described as one of "regulation plus." Bakalis v. Crossland Sav. Bank, 781 F. Supp. 140, 145 (E.D.N.Y. 1991) ("The rule that appears to emerge from the case law is one of 'regulation plus . . . '."). This line of cases was summarized in Ryan:

An examination of previous cases in which private corporations and individuals have been allowed removal under section 1442(a)(1) is helpful in establishing the indicia of official control necessary to warrant removal. The rule established is that removal by a 'person acting under' a federal officer must be predicated upon a showing that the acts that form the basis for the state civil or criminal suit were performed pursuant to an officer's direct

orders or to comprehensive and detailed regulations. Cf. <u>Bakalis v. Crossland Sav. Bank</u>, 781 F. Supp. 140, 144-45 (E.D.N.Y. 1991) ('The rule that appears to emerge from the case law is one of 'regulation plus . . .'.'). By contrast, a person or corporation establishing only that the relevant acts occurred under the general auspices of a federal office or officer is not entitled to section 1442(a)(1) removal. Likewise, the mere fact that a corporation participates in a regulated industry is insufficient to support removal absent a showing that the particular conduct being sued upon is closely linked to detailed and specific regulations. <u>Bakalis</u>, 781 F. Supp. at 144-45. Between these extremes on the 'acting under' spectrum there will, of course, be numerous close calls.

Ryan, 781 F. Supp. at 947.

Defendants' assistance to the federal government in its efforts to control the spread of COVID-19 went far beyond a mere response to federal regulation and satisfied both the Watson "instruction, direction, or guidance" and "regulation plus" tests. At the outset of the pandemic, HHS identified medical and healthcare providers as its "critical partners", and the federal government designated them as members of the nation's "critical infrastructure." The broad purpose of the PREP Act is to provide a unified, rapid federal response to a national public health threat, and to prevent critical partners from being distracted by the cost and conflicting standards of litigation in multiple forums. 85 Fed. Reg. 79,190, 79,190 and 79,191 (noting the PREP Act allows for a "unified, whole-of-nation" response). These providers had a "special responsibility" to assist the government in its efforts to mitigate the spread of the virus, continue operations, and ensure implementation of federal, state and local mandates and directives in the interest of public safety and delivery of critical infrastructure services. See e.g. HHS Ofc. of Gen Counsel, Response Letter to Thomas Baker (Aug. 14, 2020), 1, 2, n. 3; 85 Fed. Reg. at 15, 202 (state licensed facilities are "authorized in accordance with the public health and medical emergency response of the AHJ"); 85 Fed. Reg. 79,190 n. 6 (noting "authorizations that the HHS Office of the Assistant Secretary for Health (OASH) has issued as an Authority Having Jurisdiction" to Nursing Homes and Assisted Living Facilities); Id. at 79,193 n. 17 (referencing "examples" of Covered Persons "authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures"); 79,195, n. 20 (determining Nursing Homes and Assisted Living Facilities to be qualified persons and citing "Guidance for PREP Act Coverage for COVID-19 Screening <u>Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate</u> Facilities").

The PREP Act and nearly all of HHS's COVID-19 directives declare that the federal government relied on its close, directed relationship with licensed senior living communities for its "whole-of-nation" response. In fact, HHS distinguishes healthcare entities like Defendants as a subset of potential program planners. See AO 20-04. While HHS "re-emphasizes the breadth of PREP Act immunity" for potential program planners and qualified persons otherwise administering or using countermeasures, it notes that "[s]uch entities are not limited to healthcare professionals" but distinguishes "healthcare companies that are part of a government response to the COVID-19 pandemic." Id.

The PREP Act is just one component of HHS's broad authority under the larger Public Health Services Act ("PHSA"). 42 U.S.C. §201 *et seq.* (providing for the federal supervision of public/private health service provision and federal-state cooperation). Pursuant to the PHSA and the PREP Act, HHS is authorized to **deputize private entities to support the national coordinated response and set the breadth of protections in exchange for their participation. 42 U.S.C. §§247d-6d(b)(3)(A-B), (d), (i)(2), (i)(6). Congress has provided that HHS will determine which "private corporation" acting as a "person" under the PREP Act will be utilized as "program planner" and thereby be authorized to administer a countermeasure program or facility pursuant to HHS and AHJ direction. 8**

Additionally, Congress expressly refers to federal officer involvement in subsections (d)(1) and (f) of 42 U.S.C. § 247d-6d. In subsection (f), Congress provides that federal "agencies" (such as HHS), "instrumentalities" (such as AHJs, healthcare infrastructure participants, and senior living facilities), and "officers" (such as program planners) will keep federal statutory protection, such as § 1442(a), regardless of any provision of the PREP Act...§ 247d-6d(f) (emphasis added). Subsection (f) refers to the types of legal protections for federal officers, such as Defendants, by citing to "other provisions of law," "any defense protection," and "any other law" which would include the protections of §1442(a). Subsection (f) also refers to two categories of federal agents to be protected: "instrumentalities" and "officers" of HHS. Subsection (f)'s assurance of statutory protections of federal instrumentalities and officers is expressly incorporated into subsection (d)(1) of the PREP Act: "Subject to subsection (f), the sole exception to immunity from suit...shall be for an exclusive Federal cause of action..." § 247d-6d(d)(1) (emphasis added). By incorporating subsection (f) into subsection (d)(1), Congress makes clear that the creation of the PREP Act cause of action is not abrogating or limiting in any federal protection, such § 1442, that otherwise bestowed upon an instrumentality or officer on the of federal government's agencies. Thus, it is clear Congress anticipated that a public health crisis, such as the COVID-19 pandemic, would involve private federal officers and instrumentalities which would need all protections afforded by federal law, including 28 U.S.C. § 1442(a).

During the COVID-19 pandemic, HHS bolstered its healthcare infrastructure by marshaling public and private healthcare resources led by a coordinated network of government AHJs. HHS expressly likened declared program planners such as Defendants to federal contractors referring numerous times in its Declaration to PREP Act protections extending not only to those entities having federal contracts, but to those authorized under AHJs to administer, distribute, and dispense countermeasures. 85 Fed. Reg. at 15,200-15,200. HHS explains that the PREP Act protections also apply to the "officials, agents, employees, and volunteers" of AHJs such as Defendants which was a state licensed skilled nursing facility. Such direction and control during the limited period of the COVID-19 Declaration clearly illustrates federal surrogacy and substantiates the "acting under" prong of 28 U.S.C. §1442(a).9

Beginning in January 2020, in response to the pandemic and national state of emergency, CMS and the CDC, began issuing extremely detailed and pervasive directives to healthcare facilities as members of the nation's critical infrastructure and as part of the coordinated national effort to respond to and contain the COVID-19 pandemic. This included New Jersey Department of Health surveyors, contracted by CMS, supervising skilled nursing facilities with respect to infection control and pandemic responses and ensuring strict compliance with CMS directives. The issuance of real time and evolving guidance in response to a public health emergency was in contrast to the role of CMS prior to the pandemic. The COVID-19 pandemic marked a qualitative shift in the relationship and the type and scope of the regulations as well as in their purpose in directing the actions by licensed nursing facilities. Throughout the pandemic, CMS, CDC, and the NJ DOH as their agent, specifically instructed facilities to take or not take particular clinical and operational actions.

As an example, in January and February 2020 the CDC issued a number of health updates regarding COVID-19, as well as criteria to guide the evaluation and testing of patients under investigation ("PUI") for

⁹ <u>Maglioli</u>—which is not yet final and not binding misapplied the <u>Watson</u> test for federal officer jurisdiction largely out of a fear of creating a "slippery slope". <u>Maglioli</u> at *5. The Court worried that "clergy, farmers, bus drivers" may be deemed federal officers if it recognized nursing facilities as federal officers. <u>Id</u>. However such institutions do not have Letters or Declarations from HHS declaring them to be "program planners," "covered persons," "qualified persons," or "critical partners" in fighting COVID-19 under the PREP Act like Defendants in this action.

COVID-19. Healthcare providers were advised to identify PUI based on clinical features - travel to an affected geographic region and contact with a person confirmed to have tested positive for COVID-19. Persons meeting the PUI criteria were to be tested and healthcare providers were advised to immediately notify their local or state health department in the event they were evaluating a PUI. State health departments in turn were instructed to immediately contact the CDC and complete a PUI case investigation form. Initially COVID-19 testing was conducted solely through the CDC. The CDC also instructed healthcare providers to use standard, contact and airborne precautions when interacting with PUI. (See January 8, 2020, CDC Health Update Outbreak of Pneumonia of Unknown Etiology (PUE) in Wuhan China,; January 17, 2020 CDC Interim Infection Prevention and Control Recommendations for Patients with Known or Patients Under Investigation for 2019 Novel Coronavirus (2019-n-coV) in a Healthcare Setting; January 24, 2020 CDC Interim Infection Prevention and Control Recommendations for Patients with Known or Patients Under Investigation for 2019 Novel Coronavirus (2019-n-coV) in a Healthcare Setting.

Defendants' actions and conduct were taken due to unprecedented and "strong government intervention" which went beyond the "mere auspices of federal direction." See Fung v. Abex Corp., 816 F. Supp. 569, 572 (N. D. Cal. 1992). CMS told facilities when staff could report to work, when to transfer suspected or confirmed COVID positive residents to a hospital and when and how they could accept COVID-19 positive patients. CDC directed facilities when to test patients and healthcare personnel and how to prioritize testing. CDC also directed facilities on how to isolate patients. CMS ordered facilities to cancel communal activities, screen staff and residents, amend policies regarding interaction with vendors, and how to handle potential end-of-life interactions with family members, among other interventions.

Plaintiff claims that should the Court determine Defendants were program planners would mean every private business that administered masks, provided COVID-10 testing, and prioritized who could receive supplies would qualify as a federal officer. This is simply untrue, and it also untrue – as Plaintiff claims – that all other courts have rejected this argument in the pandemic contact. See Wazelle v. Tyson Foods, Inc., 2-21 U.S. Dist. LEXIS 119085 (June 25, 2021).

iii. Plaintiff's Complaint Concedes That There Exists a Significant Relationship between Defendants and the Federal Government

Plaintiff's Complaint acknowledges the significant relationship between the federal government and Defendants. The Complaint acknowledges the strong interplay between the facility and the federal government. Exhibit B at Facts, par. 20, 21. Plaintiff's Complaint also emphasizes and acknowledges the "whole-of nation" response required on nursing facility with the inclusion of the Timeline provision which specifically noted the CDC directives to healthcare facilities on February 29, 2020 (id. at par. 42) and March 15, 2020 (id. at par. 52); the New Jersey Department of Health's instructions on March 3, 2020 and March 9, 2020 (id. at par. 44 & 47); CMS directives on March 13, 2020 (id. at par. 49 & 52).

C. Plaintiff's Allegations Arise from Actions Taken by Defendants Pursuant to Federal Directives.

The next requirement, often referred to as the "nexus" or "causation" requirement, demands that the alleged conduct have been undertaken "for or relating to" a federal office. To meet this requirement, "it is sufficient for there to be a connection or association between the act in question and the federal office." Defender Ass'n, 790 F.3d at 471. Here, a clear causal nexus exists between Plaintiff's claims and the actions taken by Defendants in responding to and administering care related to the COVID-19 outbreak. Plaintiff alleges Defendants were negligent in the manner in which they allocated and utilized scarce resources and countermeasures in responding to the global crisis—all of which was done at the direction of HHS, CDC and CMS. Plaintiff complains about Defendants' allocation of PPE, and specifically, that Defendants provided masks only to registered nurses, not to others who also interacted with residents, including housekeepers, recreation therapists and nursing assistants, among other potential miscues. Plaintiff further alleges Defendants failed to properly execute existing protocols and procedures set in place to prevent the spread of the COVID-19 virus. Plaintiff specifically criticizes Defendants for not following the directives issued by CMS in the March 13, 2020 memorandum entitled "Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in Nursing Homes." Id. at par. 84.

At all relevant times, Defendants in the present action, in their preparation and response to the COVID-19 outbreak, were acting at the specific instruction and oversight of the federal government,

specifically, the HHS, CMS, and CDC in responding to a federal effort to address the ongoing national state of emergency. Defendants' actions were taken "in an effort to assist, or to help carry out, the duties or tasks" dictated by the CDC and CMS in responding to the COVID-19 pandemic. Defendants were acting specifically at the direction and under the supervision of the United States government with respect to various countermeasures implemented to prevent and treat the COVID-19 virus, including following evolving and specific guidelines from CMS and CDC with respect to: (1) infection control policies and procedures; (2) PPE procurement; (3) PPE allocation; (4) admission and discharge of residents; (5) managing visitors and outside persons, (6) staffing allocation and retention; (7) isolation protocols and management, among multiple additional directives. Thus, a nexus plainly exists between Defendants' actions under color of federal office and Plaintiff's claims.

D. Defendants Have Raised a Colorable Defense Based Upon Federal Law

Finally, Defendants have asserted a colorable federal defense including, among others, their immunity and federal preemption under the PREP Act. For the purposes of removal, the defense must merely be "colorable" and need not be "clearly sustainable" as the purpose of the removal statute is to ensure that the validity of the defense may be tried in federal court. Willingham v. Morgan, 395 U.S. 402, 407 (1969). As previously set forth, Defendants assert that they are immune from liability in this matter under the PREP Act as they meet the requirements of "covered person" as contemplated by 42 U.S.C. § 247d–6d and that the claims are preempted under the Act. (See pp. 16-24). In addition, Defendants assert that all claims are preempted by the PREP Act, and Plaintiff has failed to exhaust his federal pre-litigation administrative remedies under the PREP Act.

IV. JURISDICTION ALSO EXISTS AS PLAINTIFF'S ALLEGATIONS PRESENT A SUBSTANTIAL EMBEDDED QUESTION OF FEDERAL LAW UNDER GRABLE

The Advisory Opinions issued by HHS and the Secretary's Fourth Declaration also support the conclusion that federal jurisdiction exists here under the embedded federal issue doctrine. Under this doctrine, state law claims can give rise to federal jurisdiction when they "implicate significant federal issues." Grable, 545 U.S. at 312. The embedded federal question doctrine "captures the commonsense notion that a federal

court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." Id. A federal forum is also important when substantial federal question[s] of great federal interest are presented, even when raised by a complaint framed in terms of state law, provided that resolution of the federal question is necessary to the resolution of the state-law claim." 1 Moore's Manual-Federal Practice & Procedure § 5.10 (2020).

An issue may be substantial where the outcome of the claim could turn on a new interpretation of a federal statute or regulation which will govern a large number of cases. In other words, a case is more likely to be important to the federal system as a whole if it presents "a nearly 'pure issue of law ... that could be settled once and for all" rather than an issue that is "fact-bound and situation-specific" and whose holding will more likely be limited to the facts of the case.

Municipality of Mayagüez v. Corporación Para el Desarrollo del Oeste, Inc., 726 F.3d 8, 14 (1st Cir. 2013).

Thus, embedded federal jurisdiction may exist where "a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." <u>Gunn v. Minton</u>, 568 U.S. 251, 258 (2013) (citing <u>Grable</u>, 545 U.S. at 313-14).

In the context of the COVID-19 pandemic, which has affected every state in the country, the present case raises substantial questions concerning the application of various provisions of the PREP Act, including the broad immunity provision and the interpretation of the exception for claims involving willful misconduct, as the Secretary explicitly recognized in the Fourth Declaration:

COVID-19 is a global challenge that requires a whole-of-nation response. There are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mf'g., 545 U.S. 308 (2005), in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities. The world is facing an unprecedented pandemic. To effectively respond, there must be a more consistent pathway for Covered Persons to manufacture, distribute, administer or use Covered Countermeasures across the nation and the world. Thus, there are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mf'g., 545 U.S. 308 (2005), in having a uniform interpretation of the PREP Act.

85 Fed. Reg. at 79197.

The Declaration interprets the PREP Act as expressing Congress' intent for an exclusive federal

forum and notes that through the PREP Act, Congress delegated to the Secretary "the authority to strike the

appropriate Federal-state balance with respect to particular Covered Countermeasures through PREP Act

declarations." Id. at 79198. The Grable doctrine and PREP Act are, therefore, directly applicable to Plaintiff's

claims and support this Court's jurisdiction.

Further, AO 21-01 holds that "ordaining the metes and bounds of PREP Act protection in the context

of a national health emergency necessarily means the case belongs in federal court." This interpretation is

consistent with the Supreme Court's long-standing rule "that in certain cases federal question jurisdiction

will lie over state-law claims that implicate federal issues." Grable at 312. Here, Defendants have met the

requirements warranting federal jurisdiction. First, Plaintiff explicitly pleads claims arising from the alleged

use or administration of covered countermeasures in connection with the care and treatment provided. In

doing so, Plaintiff necessarily raises an actual disputed issue which is critical to the outcome of this case.

Furthermore, as the Advisory Opinion confirms, the express intention to have federal courts supersede and

preempt state jurisdiction with respect to the issues raised by Plaintiff. As such, these issues must be resolved

in the federal court system

CONCLUSION

Based on the foregoing, Defendants respectfully request that Plaintiff's Motion to Remand be denied

in its entirety.

/s Malinda A. Miller

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Date: January 24, 2022

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